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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------------|---------------------|------------------|
| 10/510,507   | 04/20/2005  | Jonathan Alexander Terrett | 2543-1-039PCT/US    | 2619             |
| 23565  | 7590        | 05/10/2006                 | EXAMINER            |                  |
| KLAUBER & JACKSON<br>411 HACKENSACK AVENUE<br>HACKENSACK, NJ 07601 |             |                            | AEDER, SEAN E       |                  |
|  |             |                            | ART UNIT            | PAPER NUMBER     |
|  |             |                            | 1642                |                  |

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/510,507    | <b>Applicant(s)</b><br>TERRETT, JONATHAN<br>ALEXANDER |  |
|                              | <b>Examiner</b><br>Sean E. Aeder, Ph.D. | <b>Art Unit</b><br>1642                               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 7 and 20, as specifically drawn to a method of screening for and/or diagnosing carcinoma in a subject comprising detecting and/or quantifying in a biological sample obtained from said subject a RAIG1 polypeptide.

Group II, claim(s) 1, 2, and 20, as specifically drawn to a method of screening for and/or diagnosing carcinoma in a subject comprising detecting and/or quantifying in a biological sample obtained from said subject a RAIG1 polynucleotide.

Group III, claim(s) 1-5, 7, and 20, as specifically drawn to a method of monitoring the effectiveness of a cancer therapy in a subject comprising detecting and/or quantifying in a biological sample obtained from said subject a RAIG1 polypeptide.

Group IV, claim(s) 1, 2, and 20, as specifically drawn to a method of monitoring the effectiveness of a cancer therapy in a subject comprising detecting and/or quantifying in a biological sample obtained from said subject a RAIG1 polynucleotide.

Group V, claim(s) 6 and 8, drawn to an antibody that specifically binds to one or more RAIG1 polypeptides.

Group VI, claim(s) 9, drawn to a diagnostic kit.

Group VII, claim(s) 10 and 12, as specifically drawn to a method for the treatment of carcinoma comprising administering a RAIG1 polypeptide.

Group VIII, claim(s) 10 and 12, as specifically drawn to a method for the treatment of carcinoma comprising administering a RAIG1 polynucleotide.

Group IX, claim(s) 11, drawn to a method for the treatment of carcinoma comprising administering an antibody.

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Group X, claim(s) 13, 14-17, and 18, as specifically drawn to a method of screening for anti-carcinoma agents that interact with a RAIG1 polypeptide, a method of screening for anti-carcinoma agents that modulate the activity of RAIG1 polypeptide, and an agent identified by said method.

Group XI, claim(s) 15-17, as specifically drawn to a method of screening for anti-carcinoma agents that modulate the expression of RAIG1 polypeptide.

Group XII, claim(s) 15-17, as specifically drawn to a method of screening for anti-carcinoma agents that modulate the expression of RAIG1 polynucleotide.

Group XIII, claim(s) 19, as specifically drawn to treating a carcinoma comprising administering an agent which interacts with or causes a change in the activity of RAIG1 polypeptide.

Group XIV, claim(s) 19, as specifically drawn to treating a carcinoma comprising administering an agent which causes a change in the expression of RAIG1 polypeptide.

Group XV, claim(s) 19, as specifically drawn to treating a carcinoma comprising administering an agent which interacts with or causes a change in the expression of RAIG1 polynucleotide.

The inventions listed as groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XV appears to be that they all relate to the special technical feature of a RAIG1 polypeptide.

However, Cheng et al (Journal of Biological Chemistry, 1996, 273(52): 35008-35015) teaches a RAIG1 polypeptide (Figure 3, in particular).

Therefore, the technical feature linking the inventions of groups I-XV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the

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provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Species***

Claims 1, 10, 11, 13, 15, 17, 19, and 20 are generic to a plurality of disclosed patentably distinct species of **carcinomas** comprising the following: breast cancer, pancreatic cancer, lung cancer, liver cancer, ovarian cancer, colon cancer, and osteosarcoma (see claim 20). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. Further, the above species are distinct diseases which differ at least in etiology, pathology, and mechanisms. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are

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added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER